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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	13

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

BEST AVAILABLE COPY

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/631,411	CAO ET AL.
	Examiner	Art Unit
	Karen A. Lacourciere	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 17 March 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 1-10 and 15-20 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other:

**DETAILED ACTION*****Election/Restrictions***

This application contains claims 1-10 and 15-20 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Specification***

The attempt to incorporate subject matter into this application by reference to non-patent literature is improper because the structure and physical activities of the proteins "Smad6" and "Hoxc-8" are essential to practice the claimed invention and incorporation by reference of "essential material", for example, the structural information required to describe the claimed invention in this case, may not be incorporated by reference to non-patent publications. (see MPEP 608.01(p). This objection to the specification, set forth in the prior Office action mailed 01-14-2003, is maintained. Applicant has not provided any arguments that address this objection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 are maintained as rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 11-14 are drawn to methods of screening for a compound that disrupts transcriptional repression of a gene wherein a Smad6/Hoxc-8 protein complex is formed. The specification as filed does not provide any structural information, ie. sequence, for Smad6 or Hoxc-8 such that the skilled artisan would recognize the common structural features of proteins encompassed in the terms Smad6 and Hoxc-8. It is noted that the specification incorporates by reference publications that include sequences for Smad6 and Hoxc-8 (see page 31 of the specification), however, incorporation by reference of "essential material", ie. the structural information required to describe the claimed invention in this case, may not be incorporated by reference to non-patent publications. (see MPEP 608.01(p)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 are maintained as rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-14 are indefinite due to the recitation "Smad6" and "Hoxc-8". It is unclear what proteins would be encompassed in the terms "Smad6" and "Hoxc-8", because the specification has not provided a definition for what proteins would be encompassed in these terms, or enough information on the structure of these proteins, such that the skilled artisan would know what proteins are encompassed in these terms. For example, the prior art recognized some proteins that would be encompassed by the terms "Smad6" and "Hoxc-8", because these names are used in the prior art, however, it is unclear what other proteins would be encompassed in these terms because the names assigned to proteins are not necessarily used consistently in the art. For example, what proteins would be encompassed by these terms, but referred to in the prior art by an alternative name? The specification has not provided enough structural information or characteristics of "Smad6" and "Hoxc-8" proteins such that the skilled artisan could determine what proteins are encompassed in the claims, but referred to using an alternative name.

#### ***Response to Arguments***

Applicant's arguments filed March 17, 2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 11-14 under 35 USC 112, first paragraph, set forth in the prior Office action mailed January 14, 2003

Applicant argues that well established terms or procedures do not require definitions or details. Applicants argue that possession has been shown by reduction to practice of the claimed invention and that the description need only describe in detail what is new and not conventional. Applicant argues that the specification has provided ample data on the interaction between Smad6 and Hoxc-8 using a yeast two hybrid system, co-immunoprecipitation, gel shift assays and competition assays with Smad1. Applicant argues that the practice of the invention does not require any knowledge of the structural features of Smad6 and Hoxc-8 as the invention only requires cloning of Smad6 and Hoxc-8 into suitable vectors. Applicant contends that Smad6 and Hoxc-8 are well known in the art and the ordinary skilled artisan can readily obtain published sequences for these proteins in the prior art and clone the proteins by standard methods.

These arguments have been fully considered, however, they have not been found persuasive. The specification has provided no written description for Smad6 or Hoxc-8 with regards to the structure of these proteins, which is essential to the practice of the claimed invention. Applicant relies upon the prior art for this written description, however, incorporation by reference of "essential material", for example, the structural information required to describe the claimed invention in this case, may not be incorporated by reference to non-patent publications (see MPEP 608.01(p)). The assays disclosed in the specification do not provide a description by which the skilled artisan could determine the common structural features of the genus of Smad6 and Hoxc-8 proteins used in the methods encompassed by the claims, for example, the gels

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presented in the specification do not even use molecular weight markers by which the skilled artisan could determine the weight of Smad6 or Hoxc-8. Applicant has reduced to practice assays using one species of Smad6 and one species of Hoxc-8, however, Applicant has not described the physical characteristics of either Smad6 or Hoxc-8 such that the skilled artisan would recognize that Applicant was in possession of the genus of Smad6 and Hoxc-8 proteins used in the claimed methods. Applicant acknowledges that to practice the claimed invention the skilled artisan would be required to clone Smad6 and Hoxc-8, and relies upon the prior art to teach the sequences of Smad6 and Hoxc-8. The specification, however, does not provide an adequate written description for Hoxc-8 and Smad6 such that the skilled artisan would know what sequences in the prior art to clone for Smad6 and Hoxc-8. Further, it is unclear that an adequate number of species of Smad6 and Hoxc-8 are available in the prior art to represent the genus of Smad6 and Hoxc-8 used in the methods encompassed in the claims, particularly since the specification has not provided an adequate description such that the number of prior art species can be determined.

In response to the rejection of record of claims 11-14 under 35 USC 112, second paragraph, set forth in the prior Office action, mailed January 14, 2003, Applicant argues that Smad6 and Hoxc-8 are well known, extensively studied and would be readily recognized by one of ordinary skill in the art based on the description and sequences available in the art. Applicant argues that there would be no confusion in the

art of a Smad6 or Hoxc-8 being named otherwise in the art because these proteins are so well characterized and well defined.

These arguments have been considered, but have not been found persuasive. The terms Smad6 and Hoxc-8 are simply names and do not provide a limiting definition for a protein by that name. The specification has not provided sufficient structural information or a description of physical characteristics for these proteins such that the skilled artisan could determine what proteins are encompassed in the scope of the proteins used in the claimed methods. Because the description of these proteins is insufficient it is not possible to determine if these proteins are named differently in the art, because there is insufficient description by which to search for these proteins. Therefore, the skilled artisan could not determine what proteins are or are not encompassed in the terms "Smad6" and "Hoxc-8".

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
June 2, 2003

*Karen Lacourciere*  
KAREN LACOURCIERE  
PATENT EXAMINER